DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Canon Inc. - Hiratsuka Development Center
% Izumi Maruo
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January 22, 2015

Re: K143718
Trade/Device Name: Mammography Color Display DP-M3010
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: December 19, 2014
Received: December 29, 2014

Dear Izumi Maruo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143718

Device Name
DP-M3010

Indications for Use *(Describe)*
The DP-M3010 is intended to be used in displaying and viewing digital images, including digital mammography for review and analysis by trained medical practitioners.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

a. Owner/Company name, address

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c. Date prepared

December 19, 2014

d. Name of device

Trade Name:	Mammography Color Display DP-M3010
Common Name:	System, Image Processing, Radiological
Classification Name:	Picture archiving and communications system
Classification Regulation:	21 CFR 892.2050
Product Code:	PGY

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e. Predicate devices

The Mammography Color Display DP-M3010 (hereinafter the DP-M3010) is substantially equivalent to the following legally marketed device:

510(k) Number	Trade name
K120451	RadiForce RX840-MG

The predicate device is hereinafter called “RadiForce (K120451)” in this application.

f. Description of the device

The DP-M3010 is intended to be used in displaying and viewing digital images, including digital mammography, for review and analysis. The DP-M3010 is consisted of the DP-M3010 display and the application software including Quality Control and Display Configuration Software. For the DP-M3010 display, 30-inch 10MP color LCD panel is used. The resolution is 10.5 megapixel (4096 x 2560). The DP-M3010 display has following two functions;

- The hybrid view function: Monochrome compliant with the DICOM part 14 standard and color with non-DICOM gamma images are displayed on one screen at the same time.
- The Contrast Enhancer function: Darkening the background of images.

The DP-M3010 has the built-in front sensor for monitoring display status. Using this front sensor allows for automatic correction of differences between the display characteristics that may change over time and the target image quality of the display. Also, The DP-M3010 has the ambient light correction function, namely correcting the luminance and gradation according to surrounding light by using the built-in ambient light sensor.

The Quality Control is software to be installed in a computer which controls the DP-M3010 display. The Quality Control software executes the calibration function, runs tests compliant with various testing standards, creates test result reports, and monitors the DP-M3010 display conditions. The Display Configuration Software is used to perform the display settings. It is possible to save settings of the DP-M3010 Display on the computer. It is also possible to manually edit the areas for the hybrid view function.

g. Indications for Use

The DP-M3010 is intended to be used in displaying and viewing digital images, including digital mammography for review and analysis by trained medical practitioners.

h. Statement of substantial equivalence

The DP-M3010 has the same intended use as the RadiForce (K120451) as shown in Table 6-1. Comparison Table of Technological Characteristics.
Regarding differences of technological features between the DP-M3010 and the RadiForce (K120451) in Table 6-1, the non-clinical testing demonstrates that those differences do not raise any new questions of safety or effectiveness (The summaries of the non-clinical testing are shown in next part in this section).

Comparison Table of Technological Characteristics is shown below.

Table 6-1. Comparison Table of Technological Characteristics

Feature	DP-M3010	RadiForce (K120451)
Classification	892.2050	892.2050
Intended Use	The DP-M3010 is intended to be used in displaying and viewing digital images, including digital mammography for review and analysis by trained medical practitioners.	The RadiForce RX840-MG is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.
Display Performance /Specification		
Screen technology	TFT Color LCD panel(IPS)	TFT Color LCD panel(IPS)
Screen surface	Anti-Reflection	Anti-Glare
Viewing angle (Horizontal, Vertical)	Horizontal:170°, Vertical:170° (CR > 50)	Horizontal:176°, Vertical:176° (CR > 10)
Active screen size	645.12 x 403.2 mm	817.1 x 430.9 mm
Resolution	10.5 MP(4,096 x 2,560)	8MP(4,096 x 2,160)
Aspect ratio	16:10	17:9
Pixel pitch	0.1575 x 0.1575 mm	0.1995 x 0.1995 mm
Maximum luminance	500 cd/m^2	700 cd/m^2
DICOM calibrated luminance	500 cd/m^2	500 cd/m^2
Contrast ratio	1000:1	1000:1
Backlighting	LED	LED
Gradation	10 bit	8 bit, 10 bit
Luminance non-uniformity compensation	Yes	Yes
Response speed	20 ms（black-white-black）	25 ms（black-white-black）
Video Signal Input		
Input video signals	DisplayPort 1.1a x 4	DVI-D(Dual Link) x2, DisplayPort x 2
Scanning Frequency(V)	59.922 - 60.317Hz	29.5 - 61Hz
Dot Clock	174.25MHz x4	DVI-D: 310MHz DisplayPort: 290MHz
Power Related Specifications		
Power Requirements	AC 100 - 240V : 50/60Hz	AC 100 - 120V, 200 - 240V : 50/60Hz

Power Consumption / Save Mode	325W / 2W	350W / 6W
Power Management	DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a
Miscellaneous Features/ Specifications		
QC software	Yes	Yes
Sensors	Backlight Sensor, Front Sensor, Ambient Light Sensor	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0
Dimensions w/o stand (W x H x D)	707 x 465 x 106 mm	896 x 527 x 157 mm
Contrast Enhancer (Darkening image Background)	Yes	No

The DP-M3010 has the "Contrast Enhancer" function which can be used to darken the background of images, however, the RadiForce (K120451) does not have this function. Canon concluded that this function does not raise any new questions of safety or effectiveness because of following reasons;

- The Contrast Enhancer darkens background only.
- User can set on or off the Contrast Enhancer as if necessary.
- Device performance was not affected whether the Contrast Enhancer was on or off in performance testing.

The DP-M3010 does not have the presence sensor which is included in the RadiForce (K120451). The sensor only detects the presence or absence of the user. Therefore, the display performance for clinical situation is unaffected by the presence sensor.

Based on the above, all the differences between the DP-M3010 and the RadiForce (K120451) do not raise any new concern. Thus, the DP-M3010 is substantially equivalent to the RadiForce (K120451).

i. Non-Clinical Performance Summary

The following bench tests were performed on the DP-M3010. Those tests are recommended in "Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions".

- Luminance response
- Luminance uniformity
- Geometrical distortion
- Display reflections including specular, diffuse, and haze components
- Small-spot contrast ratio

- Spatial resolution expressed as modulation transfer function (MTF)
- Noise expressed as noise power spectrum (NPS)
- Pixel aperture ratio
- Chromaticity measured at the center of the screen at 5%, 50%, and 95% of the maximum luminance
- Chromaticity uniformity
- Pixel defect/faults
- Artifacts
- Temporal response
- Stability of luminance

Those test results showed that the display performance of the DP-M3010 is equivalent to that of the RadiForce (K120451).

In addition to those bench tests, electrical safety in accordance with IEC 60601-1 and EMC in accordance with IEC 60601-1-2 tests were performed. Those test results indicate that the DP-M3010 does not raise concern.

No animal or clinical testing was performed on the DP-M3010.

j. Conclusion

The DP-M3010 and the RadiForce (K120451) have the same intended use and the TFT Color LCD panel (IPS) screen. However, there are some different technological characteristics. Non-clinical tests showed that the different technological characteristics do not raise safety and effectiveness concern. Therefore, Canon concluded that the DP-M3010 is substantially equivalent to the RadiForce (K120451).